UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SUBHASH PATEL, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

– against –

KONINKLIJKE PHILIPS N.V., FRANS VAN HOUTEN, ANHIJIT BHATTACHARYA, and JOHN FRANK,

Defendants.

NOT FOR PUBLICATION

MEMORANDUM & ORDER

21-cv-4606 (ERK) (MMH)

KORMAN, *J.*:

Lead Plaintiff Richard Sun and Plaintiff Subhash Patel (together, "Plaintiffs") bring this putative securities class action against Defendant Koninklijke Philips N.V. ("KPNV") and Individual Defendants Frans van Houten, Abhijit Bhattacharya, and John Frank (together, "Defendants"), alleging violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1924 ("Exchange Act"). KPNV, van Houten, and Bhattacharya have moved to dismiss the Second Amended Complaint (the "Complaint"); Frank joined the motion in its entirety and also moved separately to dismiss the Complaint. The motions are granted in part and denied in part.

BACKGROUND

KPNV is a multinational health technology *naamloze vennootschap*, a corporation organized under Dutch law, headquartered in Amsterdam. Second Am.

Compl. ¶¶ 57, 67 [hereinafter "SAC"]. KPNV's common shares trade on the New York Stock Exchange ("NYSE") under the ticker symbol "PHG."[1] *Id.* ¶ 57. Among KPNV's many subsidiaries is Philips Respironics, Inc. ("Philips Respironics"), a Delaware corporation headquartered in Pennsylvania. *Id.* ¶ 57.

Defendant François Adrianus "Frans" van Houten was the Chief Executive Officer ("CEO") of KPNV at all relevant times. *Id.* ¶ 58. Defendant Abhijit Bhattacharya was the Chief Financial Officer ("CFO") of KPNV at all relevant times. *Id.* ¶ 59. Both were members of KPNV's Board of Management and Executive Committee. *Id.* ¶¶ 58–59. Defendant John Frank was the CEO of Philips Respironics at all relevant times, and he also served as the leader of Sleep & Respiratory Care, a division within KPNV. *Id.* ¶ 60.

Plaintiffs Richard Sun and Subhash Patel are investors in KPNV common stock on the NYSE. *Id.* ¶¶ 55–56. The Complaint alleges that they purchased KPNV common stock at artificially inflated prices and suffered losses when the price of the stock fell in the aftermath of KPNV's disclosure of a product defect. *Id.* ¶¶ 55–56. Plaintiffs sue individually and on behalf of a putative class of persons and entities who purchased or otherwise acquired KPNV common stock on the NYSE during the

[1] KPNV's common shares also trade on the Amsterdam Euronext Exchange. As the parties agree, this action concerns only claims arising out of purchases on the NYSE.

period from February 23, 2016, through November 1, 2022, inclusive (the "Class Period"). *Id.* ¶ 1.

KPNV is organized into three main segments: Personal Health, Connected Care, and Diagnosis & Treatment. *See* Koninklijke Philips NV, Annual and Transition Report of Foreign Private Issuers (Form 20-F), at ch. 6.3 (Feb. 25, 2020). These segments are further divided into divisions; as relevant here, one of the divisions within Connected Care is known as "Sleep & Respiratory Care." *Id.*

Throughout the Class Period, Philips Respironics manufactured several products for the Sleep & Respiratory Care division—Bi-Level Positive Airway Pressure ("BiPAP"), Continuous Positive Airway Pressure ("CPAP"), and mechanical ventilator devices designed for the purpose of assisting individuals with sleep, breathing, and respiratory conditions, such as sleep apnea. SAC ¶¶ 67–71, 93. Specific products included: the Trilogy devices (the Trilogy 100 and Trilogy 200); the Dream Family devices (the DreamStation and DreamStation Go); and the E30, a ventilator produced in response to the COVID-19 pandemic. *Id.* ¶¶ 94–100.

All of these devices used polyester-based polyurethane ("PE-PUR") foam for sound abatement purposes. *Id.* ¶ 2. As the Complaint alleges, as early as 2015, Philips Respironics began receiving complaints from users about degradation of the PE-PUR foam, which could break into particles, enter a device's air pathway, and be ingested or inhaled by the user. *Id.* ¶¶ 4–5. Users' complaints also indicated that

they experienced headaches, upper airway irritation, coughing, chest pressure, and sinus infections in connection with use of the devices. *Id.* ¶ 5.

Internally, Philips Respironics investigated the complaints and produced reports documenting foam degradation in their Trilogy devices. *Id.* ¶¶ 6, 156. Neither Philips Respironics nor KPNV spoke publicly of the foam degradation issues or the complaints, however, until April 26, 2021, when KPNV disclosed for the first time that user reports and testing had led to the discovery of a quality issue in certain Sleep & Respiratory Care products. *Id.* ¶ 9, 334; *see also* ECF No. 48-12 at 3–4. KPNV also disclosed that it had taken a loan loss provision of €250 million to cover the cost of repairing devices. SAC ¶¶ 9, 336; *see also* ECF No. 48-12 at 5.

In June 2021, KPNV took the further step of issuing a recall of twenty products, including the Trilogy 100, Trilogy 200, DreamStation, DreamStation Go, and E30. SAC ¶ 12; *see also* ECF No. 48-17 at 3. The Food & Drug Administration ("FDA") later classified the recall as a Class I recall, the most serious category, for "situation[s] in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." SAC ¶ 15. The following month, KPNV announced that it would take an additional €250 million loan loss provision to account for the cost of the recall. *Id.* ¶ 16.

On the news of these events, KPNV's stock price fell. Specifically, after the disclosure of the foam issues, the stock price fell $2.32 per share, or 3.8%, to close

at $58.70 per share on April 26, 2021. *Id.* ¶ 11. After the announcement of the recall, KPNV's stock price fell $2.25 per share, or 3.98%, to close at $54.25 per share on June 14, 2021. *Id.* ¶ 14. And after KPNV reported that it would increase the size of its loan loss reserve, the stock price fell $1.80 per share, or 3.75%, to close at $46.14 on July 26, 2021. *Id.* ¶ 17. KPNV's stock price continued to fall, in the aftermath of the disclosure of the foam issues. *See id.* ¶¶ 32–49. On November 2, 2022, the end of the Class Period, KPNV's stock price was $11.75 per share. *Id.* ¶ 49.

Thus, Plaintiffs allege that during the Class Period, Defendants deceived investors by making materially false or misleading statements or omissions. *See id.* ¶ 474. These statements pertained to: KPNV's commitment to compliance, quality, and safety; KPNV's business and products; KPNV's financial performance and sales; and the size of the loan loss reserve and the scope of the foam issues. *See id.* ¶¶ 158–341.

To support their allegations, Plaintiffs rely primarily on Form 483, a report issued by the FDA following a site investigation of Philips Respironics, where the recalled products were manufactured. *See id.* ¶¶ 19–28, 103 & n.1. Form 483 observed, *inter alia*, that Philips Respironics had inadequate risk analysis, that Philips Respironics had not adequately established procedures for corrective and preventive action, that a correction made to reduce a health risk posed by a device was not reported to the FDA, and that management with executive responsibility had

not ensured that the quality policy was understood, implemented, and maintained at all levels of the organization. *See* ECF No. 48-19 ("Form 483").

Defendants bring the instant motions to dismiss the Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, contending that Plaintiffs have failed adequately to plead actionable misstatements and scienter.

LEGAL STANDARDS

I. Pleading Standards

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).[2] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In considering a motion to dismiss under Rule 12(b)(6), I must "construe the complaint liberally, accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017).

A complaint alleging securities fraud must also satisfy the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure and the

[2] Unless otherwise indicated, all internal quotation marks, citations, alterations, emphases, and footnotes are omitted from case citations.

Private Securities Litigation Reform Act of 1995 ("PSLRA"). *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014). Rule 9(b) requires a party to state "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The PSLRA provides that "the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). While Rule 9(b) allows a party to plead state of mind with generality, *see* Fed. R. Civ. P. 9(b), the PSLRA raises the bar, commanding that "the complaint shall, with respect to each act or omission . . . , state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u-4(b)(2)(A). "Although pleading standards are heightened for securities fraud claims, we must be careful not to mistake heightened pleading standards for impossible ones." *Altimeo Asset Mgmt. v. Qihoo 360 Tech. Co.*, 19 F.4th 145, 150 (2d Cir. 2021).

II. Section 10(b) and Rule 10b-5 Claims

Section 10(b) of the Exchange Act prohibits the "use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b-5, promulgated thereunder, enforces section 10(b) by making it unlawful "[t]o

make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b).

To state a claim for relief under section 10(b) and Rule 10b-5, "a plaintiff must allege that the defendant: (1) made misstatements or omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which plaintiffs relied; and (5) that plaintiffs' reliance was the proximate cause of their injury." *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 463 (2d Cir. 2019).

A. Scienter

The second element of a section 10(b) and Rule 10b-5 claim, scienter, is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007). A plaintiff may establish a strong inference of scienter by "alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 212 (2d Cir. 2020).

"Sufficient motive allegations 'entail concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged.'" *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001) (quoting *Novak v. Kasaks*, 216 F.3d 300, 307 (2d Cir. 2000)). "Motives that are generally possessed by most corporate

directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." *Id.*

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." *Id.* at 142.

> Securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.

Id. (quoting *Novak*, 216 F.3d at 308).

Furthermore, to allege a strong inference of scienter, "it is not sufficient to set out 'facts from which, if true, a reasonable person *could* infer that the defendant acted with the required intent,' for that gauge 'does not capture the stricter demand Congress sought to convey in [the PSLRA].'" *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110–11 (2d Cir. 2009) (quoting *Tellabs*, 551 U.S. at 314). Rather, to qualify as strong, "an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 111 (quoting *Tellabs*, 551 U.S. at 314).

B. Material Misrepresentations or Omissions

To satisfy the first element of a section 10(b) and Rule 10b-5 claim, a plaintiff may allege either affirmative misstatements or omissions of material facts. The complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Gamm*, 944 F.3d at 462. The "plaintiffs must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004).

In addition, the alleged misstatements or omissions must be material. To fulfill the materiality requirement, "there must be a substantial likelihood that [the statement or] the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988). "Because materiality is a mixed question of law and fact, in the context of a [Rule 12(b)(6)] motion, a complaint may not properly be dismissed on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009).

III. Section 20(a) Claims

Section 20(a) of the Exchange Act establishes joint and several liability, subject to a good faith exception, for "[e]very person who, directly or indirectly, controls any person liable under any provision of [the Exchange Act]." 15 U.S.C. § 78t(a). To state a claim under section 20(a), "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

To establish the second element of a section 20(a) claim, a plaintiff must show that the defendant had "the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 C.F.R. § 240.12b-2(4); *see also S.E.C. v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472–73 (2d Cir. 1996). "To be liable as a control person, the defendant 'must actually possess, in fact, rather than in theory, the ability to direct the actions of the controlled person.'" *In re Global Crossing, Ltd. Sec. Litig.*, No. 02 Civ. 910, 2005 WL 1875445, at *3 (S.D.N.Y. Aug. 5, 2005) (quoting *Wallace v. Buttar*, 239 F. Supp. 2d 388, 396 (S.D.N.Y. 2003), *reversed and remanded on other grounds*, 378 F.3d 182 (2d Cir. 2004)). Moreover, the defendant "must not only have actual control over the primary violator, but have actual control over the *transaction*

in question." *In re Alstom SA*, 406 F. Supp. 2d 433, 487 (S.D.N.Y. 2005). "Because fraud is not an essential element of a section 20(a) claim, Plaintiffs need not plead control in accordance with the particularity required under Rule 9(b)." *McIntire v. China MediaExpress Holdings, Inc.*, 927 F. Supp. 2d 105, 122 (S.D.N.Y. 2013).

To satisfy the third element of a section 20(a) claim, the plaintiff must allege facts showing that the defendant was a "culpable participant" in the fraud. However, the degree of particularity required is not entirely clear.

> Some district courts assume that "culpable participation" requires proof of state of mind, and thus conclude that plaintiffs must allege the controlling person's scienter to state a prima facie Section 20(a) claim. Other district courts have reasoned that there is no basis for equating "culpable participation" with scienter, so that plaintiffs asserting a Section 20(a) claim need allege only an underlying primary violation and control person status.

In re Philip Servs. Corp. Sec. Litig., 383 F. Supp. 2d 463, 486 & n.13 (S.D.N.Y. 2004). Because most courts in this Circuit seem to interpret "culpable participation" as the former—that is, as requiring scienter—I follow that approach here. Thus, plaintiffs must "plead with particularity facts giving rise to a strong inference that the controlling person knew or should have known that the primary violator, over whom that person had control, was engaging in fraudulent conduct." *In re Alstom SA*, 406 F. Supp. 2d at 491; *see also McIntire*, 927 F. Supp. 2d at 122–23 ("In order to withstand a motion to dismiss, a § 20(a) claim must allege, at a minimum,

particularized facts of the controlling person's conscious misbehavior or recklessness.").

DISCUSSION

Plaintiffs allege violations of section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants and violations of section 20(a) of the Exchange Act against the Individual Defendants.

I. Plaintiffs' Section 10(b) and Rule 10b-5 Claim

Defendants move to dismiss the Complaint on the grounds that Plaintiffs have failed adequately to allege either scienter or material misstatements. For the reasons set forth below, the motions to dismiss the section 10(b) and Rule 10b-5 claims are granted in part and dismissed in part.

A. Plaintiffs Plead a Strong Inference of Scienter

To fulfill the scienter element of a section 10(b) and Rule 10b-5 claim, Plaintiffs first offer several theories of the Individual Defendants' motives to commit fraud. However, their factual allegations are insufficient to establish such motive. Namely, Plaintiffs contend that the Individual Defendants sought to avoid or delay a product recall, avoid losing market share, and artificially inflate and maintain the market price. SAC ¶¶ 362, 386, 410–11, 472. But these purported motives are general to most corporate directors and officers, and none of the allegations contain any suggestion of "concrete and personal" benefits to the Individual Defendants.

Kalnit, 264 F.3d at 139. To the contrary, judicially noticeable SEC filings indicate that van Houten and Bhattacharya generally increased their stockholdings throughout the Class Period and that KPNV repurchased shares. *See* ECF No. 48-6 at 18, 20, 31; ECF No. 48-7 at 6, 13; ECF No. 48-8 at 6, 27; ECF No. 48-9 at 7, 14; ECF No. 48-10 at 8–9, 25; ECF No. 48-11 at 8, 13. Such behavior is inconsistent with the argument that Defendants had a motive to defraud investors.

In addition to motive, Plaintiffs seek to plead scienter by offering allegations of strong circumstantial evidence of Defendants' conscious misbehavior or recklessness. Addressing the evidence pertaining to each of the Individual Defendants in turn, I agree that Plaintiffs have adequately alleged facts giving rise to a strong inference of scienter as to Frank and van Houten, but not as to Bhattacharya. In addition, scienter may be imputed from van Houten to KPNV.

1. John Frank

To begin, Plaintiffs' allegations are sufficient to establish the scienter of John Frank, the CEO of Philips Respironics. Form 483's observations establish that "your firm [Philips Respironics] became aware of [the PE-PUR foam degradation] issue and related field complaints in at least 2015 or earlier." Form 483 at 25; *see also* SAC ¶ 411. Frank's high-level position at the "firm"—he was both the CEO of Philips Respironics and the leader of KPNV's Sleep & Respiratory Care division—suggests that he knew or should have known about the foam issues affecting his

company's products, and accordingly constitutes circumstances indicating conscious behavior by Frank. And while this is enough to establish Frank's scienter from 2015 onward, the inference of Frank's scienter is even stronger after early 2020, when Form 483 indicates that "foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020."[3] Form 483 at 25; *see also* SAC ¶ 410.

Frank's efforts to minimize the significance of Form 483's findings are unavailing. First, Frank contends that Form 483's failure to mention Frank is a barrier to finding scienter. But the report *does* mention Frank, albeit not by name, where it references "firm management, including management with executive responsibility." Form 483 at 25. Frank, as the CEO of Philips Respironics and leader of the Sleep & Respiratory Care division, is included in this group. *See id.* (explaining that "Management with Executive Responsibility," as defined by Philips Respironics, included the "Sleep and Respiratory Care Business Leader"). Second, Frank argues that the information in 2015 merely established he had access to raw data about foam degradation. But Frank offers nothing to support the proposition that Form 483's reference to "this issue and related field complaints" merely refers

[3] Plaintiffs do not identify any alleged misstatements made by Frank after 2020, but they contend that he is liable for post-2020 statements made by van Houten, Bhattacharya, and KPNV under the group pleading doctrine. The applicability of this doctrine is discussed *infra*.

to raw data, Form 483 at 25, and the more natural inference from Form 483's findings is that management knew of the foam degradation issues that led to the eventual product recalls. Accordingly, there is a strong inference that Frank acted with the requisite scienter with respect to statements attributable to him and made after 2015.

2. Frans van Houten

Next, turning to KPNV's CEO Frans van Houten, Plaintiffs likewise allege sufficient circumstantial evidence to give rise to a strong inference of scienter. They have pleaded that van Houten attended KPNV's Quality & Regulatory Committee ("QRC") meetings between 2018 and 2021, where post-market surveillance—i.e., monitoring of a medical device after it is released on the market—was discussed. After the foam issues were made public, van Houten stated that he had learned about the problems from post-market surveillance—ostensibly, the post-market surveillance discussed at the QRC meetings. *See* SAC ¶¶ 132, 337, 344, 346, 348, 391. Thus, with reference to particularized facts—namely the frequency and content of the QRC meetings—Plaintiffs have sufficiently pleaded an inference of van Houten's scienter.

Defendants seek to undermine these allegations in two ways. First, they argue that Plaintiffs do not state precisely what van Houten learned at which QRC meetings. But Plaintiffs' inability to provide exact details is not fatal to their claim. "Where plaintiffs contend defendants had access to contrary facts, they must

specifically identify the reports or statements containing this information." *Novak*, 216 F.3d at 309. Plaintiffs have done so here, identifying the QRC meetings as the place where van Houten learned about the foam issues, specifically through discussions about post-market surveillance. *See also Tellabs*, 551 U.S. at 326 ("[While] omissions and ambiguities count against inferring scienter, . . . the court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically."). Defendants also contend it is implausible that the QRC meetings discussed post-market surveillance for each of its products sold by KPNV's over 300 subsidiaries. But Plaintiffs do not allege that each product of each subsidiary was discussed in depth at each meeting—rather, Plaintiffs allege only that post-market surveillance revealing the foam issues was raised at a QRC meeting attended by van Houten. That allegation—that the parent company would have discussed post-market surveillance suggesting there were product defects in the devices of one of its subsidiaries—is both plausible and readily inferable. Thus, drawing all reasonable inferences in Plaintiffs' favor, they have established van Houten's scienter as of early to mid-2018, after he had attended a QRC meeting.[4]

[4] Plaintiffs also rely on the allegations of two confidential witnesses to strengthen the inference of scienter. As explained below, certain of these allegations cannot be credited on a motion to dismiss. In any case, these allegations are not necessary to the finding of a strong inference of van Houten's scienter.

The first confidential witness ("CW 1") was a Vice President of Sales at Philips Respironics from 2008 to 2019, whose two supervisors reported directly to Frank and one of whom "ran the CPAP product"; and the second confidential witness

3. Abhijit Bhattacharya

Unlike with Frank and van Houten, Plaintiffs' allegations are insufficient to establish an inference of scienter as to Abhijit Bhattacharya, KPNV's CFO. Plaintiffs allege only Bhattacharya's knowledge of KPNV products, as evidenced by his discussion of the devices and references to specific information; Bhattacharya's high-level position and access to information; and a Department of Justice

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("CW 2") was a Business Marketing Manager in Sleep & Respiratory Care from 2006 and 2021 who helped launch the CPAP and BiPAP products. SAC ¶¶ 65–66. CW 1 alleged that Frank frequently traveled to the Netherlands, where KPNV's headquarters were located, as well as that van Houten often visited the United States and held "frequent meetings" with Frank and CW 1's two supervisors. *Id.* ¶ 414. CW 2 corroborated these allegations. *Id.* CW 1 also alleged that the foam issues "would have been escalated to van Houten given their importance to the Company's bottom line." *Id.*

Here, Plaintiffs have described CW 1 and CW 2 with sufficient particularity to support their allegations that Frank and van Houten had frequent meetings, in which Frank would keep van Houten apprised of business developments. That is, CW 1's and CW 2's positions and involvement in Philips Respironics renders it probable that they knew about the nature of Frank and van Houten's reporting relationship. *See Novak*, 216 F.3d at 314 (explaining that for a court to credit a confidential source at the pleading stage, the source need only be "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged").

However, CW 1's allegation that the foam issues "would have been escalated to van Houten" is too speculative to credit. "[C]onfidential source allegations must show that individual defendants actually possessed the knowledge highlighting the falsity of public statements; conclusory statements that defendants were aware of certain information, and mere allegations that defendants would have or should have had such knowledge is insufficient." *In re Nielsen Holdings plc Sec. Litig.*, 510 F. Supp. 3d 217, 228–29 (S.D.N.Y. 2021). Accordingly, these allegations by the confidential witnesses are too conclusory to be relied on.

investigation into Philips Respironics and other KPNV subsidiaries focusing on the events leading to the recall. *See, e.g.*, SAC ¶¶ 37, 260, 308–09, 438.

These allegations lack particularized facts giving rise to a strong inference of scienter. Bhattacharya's statements focused on the performance and growth in various sectors of the business, and most of his statements do not mention specific devices. *See, e.g.*, *id.* ¶¶ 218, 232, 265, 268, 274, 292, 299, 308, 315–16, 323. In those statements that do name specific devices, the "discussion" is incidental to the financial reporting and limited to Bhattacharya stating, for instance, that "[t]he successful DreamWear Full Mask range continued its strong momentum delivering double-digit growth for masks overall." *Id.* ¶ 256; *see also, e.g.*, *id.* ¶¶ 240, 260. Only in one statement did Bhattacharya discuss the operation of a device, stating that "[t]he E30 is basically a modified BiPAP." *Id.* ¶ 309. That statement does not suggest Bhattacharya had knowledge of the foam issues, let alone an intent to deceive, manipulate, or defraud.

Nor is Bhattacharya's high-level position alone sufficient to create an inference of scienter. Plaintiffs do not allege that Bhattacharya had "knowledge of facts or access to information contradicting [his] public statements," nor any circumstances indicating conscious misbehavior. *Novak*, 216 F.3d at 308; *see In re Aegon N.V. Sec. Litig.*, No. 03 Civ. 603, 2004 WL 1415973, at *17 (S.D.N.Y. June 23, 2004) (finding allegations "that the Defendants had access to adverse

undisclosed information because of their senior positions with the company" to be "insufficient to establish scienter"). The mere existence of an investigation is likewise insufficient. *See Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 277 F. Supp. 3d 500, 516 (S.D.N.Y. 2017) ("The existence of a subpoena does not, without more, give rise to a strong inference of scienter on the part of senior management."). Thus, Plaintiffs' allegations do not permit a strong inference of Bhattacharya's scienter.

4. KPNV

Because Plaintiffs have sufficiently alleged van Houten's and Frank's scienter, I next turn to whether their scienter may be imputed to KPNV for purposes of the corporation's liability. To impute an individual defendant's scienter to a corporation, "the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter," or the allegedly misleading statements must "have been approved by corporate officials sufficiently knowledgeable about the company to know that the [statement] was false." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195–96 (2d Cir. 2008).

To begin, if Frank's scienter can be imputed to KPNV, then KPNV's scienter would be established as of 2015. Plaintiffs contend that Frank's scienter can be imputed for four reasons: because (1) he held a "dual role" at Philips Respironics and KPNV, as shown by Frank's LinkedIn profile; (2) Frank reported directly to van

Houten, was involved in the daily affairs of the business at the highest level, and participated in the management of KPNV, as alleged by a confidential witness; (3) regardless of whether he worked for Philips Respironics or KPNV, Frank was "deputized" to KPNV because he led the Sleep & Respiratory Care division, which was part of KPNV; and (4) Frank supplied information to KPNV for inclusion in public filings and disclosures, and therefore had ultimate authority over the statements made in official filings. *See* SAC ¶¶ 412–14.

Each of these arguments is flawed. First, KPNV's official filings, such as its Form 20-Fs, do not indicate that Frank ever held a role at KPNV. *See, e.g.*, ECF No. 48-5 at 25–32. As a result, Frank's scienter cannot be imputed to KPNV by virtue of his alleged employment there. *See also In re Aegon N.V. Sec. Litig.*, 2004 WL 1415973, at *5 ("The truth of factual allegations that are contradicted by documents properly considered on a motion to dismiss need not be accepted."). Second, it is not enough for Plaintiffs to allege simply that Frank was involved in the management of KPNV; to impute scienter, there typically must be some connection to the alleged misstatements. *See Jackson v. Abernathy*, 960 F.3d 94, 98 (2d Cir. 2020) (per curiam) (explaining that scienter may be imputed from "officers or directors *who were involved in the dissemination of the fraud*" (emphasis added)). Third, Plaintiffs' argument that Frank was "deputized" to KPNV is too conclusory—to support such an claim, Plaintiffs must allege more than the mere fact that Frank

was the leader of the Sleep & Respiratory Care division. And finally, Plaintiffs have not pleaded particularized facts about what information Frank supplied, either in reporting directly to van Houten or to KPNV for its filings. *See Valentini v. Citigroup, Inc.*, 837 F. Supp. 2d 304, 317 (S.D.N.Y. 2011) ("[T]he mere existence of a parent-subsidiary or affiliate relationship is not on its own sufficient to impute the scienter of the subsidiary to the parent or affiliate. Instead, plaintiffs must demonstrate that the parent or affiliate possessed some degree of control over, or awareness about, the fraud."). Accordingly, Plaintiffs have not shown that Frank's scienter can be imputed to KPNV.

However, van Houten's scienter is easily imputed to KPNV, given his role as its CEO. *See Thomas v. Shiloh Indus., Inc.*, No. 15 CV 7449, 2017 WL 2937620, at *3 & n.1 (S.D.N.Y. July 7, 2017) (collecting cases in which "management level" employees had their scienter imputed to corporations). Thus, the scienter element is met for KPNV, as of early to mid-2018.

B. Plaintiffs Plead Material Misrepresentations or Omissions

To fulfill the first element of a section 10(b) and Rule 10b-5 claim, Plaintiffs identify a multitude of statements that they allege were materially false or misleading. These statements generally fall into one of five categories: (1) statements about KPNV's commitment to compliance, quality, and safety; (2) statements about the business and specific products; (3) statements about

KPNV's financial performance and sales; (4) statements about the loan loss reserve and the scope of the foam issues; and (5) statements by John Frank. Addressing each category of statements in turn, I agree with Plaintiffs that certain statements in the first two categories are actionable.[5]

1. Statements About Compliance, Quality, and Safety

To begin, Plaintiffs allege that Defendants' numerous statements about KPNV's commitment to quality, compliance, and safety were materially false and misleading. The identified statements were principally made in KPNV's Form 20-Fs from the years 2015 to 2020. *See* SAC ¶¶ 159–63, 185–87, 213–14, 248–51, 279–83, 330–31. Plaintiffs also identify three other statements about compliance, quality, and safety: one made by van Houten on an October 2017 quarterly earnings call; one made by van Houten in KPNV's 2017 Annual Report to Shareholders; and one made in a March 13, 2019, press release by "Philips' Chief Medical liaison" Teofilo Lee-Chiong.[6] *See id.* ¶¶ 206, 208, 270. Plaintiffs contend that these

[5] Plaintiffs' alleged misstatements include statements that are inactionable because they were not made with the requisite scienter—that is, they were made by van Houten or KPNV before mid-2018, or they were made by Bhattacharya. *See* SAC ¶¶ 158–64, 166–68, 170–71, 173–75, 177–78, 180–83, 185–88, 190–91, 193–94, 196–98, 200–02, 204–06, 208–11 (statements made before mid-2018); *id.* ¶¶ 218, 232, 240, 256, 260, 265, 268, 274, 292, 299, 308–09, 315–16, 323 (statements made by Bhattacharya). The analysis in this section considers only those statements for which the scienter element has been met.

[6] The statement made by Lee-Chiong is inactionable because Plaintiffs have not alleged that Lee-Chiong had the requisite scienter. And even if he did, his statement—"[t]he safety of patients who use our devices is our top priority"—

statements were misleading because, at the time they were made, KPNV knew of—but failed to disclose—ongoing problems with and complaints about the foam. *See, e.g.*, *id.* ¶¶ 254. Plaintiffs also allege that the statements were false because Defendants were not actually in compliance with applicable regulations. *See, e.g.*, *id.* ¶ 131.

As a preliminary matter, there is no merit to Defendants' contention that Form 483 cannot be used to establish the falsity of their statements. It is well-established that in reviewing a motion to dismiss, I must accept as true the facts alleged in the complaint and contained in documents integral to and relied upon by the complaint. *In re Aegon N.V. Sec. Litig.*, 2004 WL 1415973, at *5. Thus, even though Form 483's observations do not represent the FDA's final determination of noncompliance, I am required to accept them as true. Additionally, while Form 483 concerned Philips Respironics, rather than KPNV, its observations remain relevant to van Houten's and KPNV's statements because, as discussed above, Plaintiffs have adequately alleged that the critical information referenced in Form 483 was known to key figures at KPNV.

Relying on Form 483, Plaintiffs have alleged that: by October 2015, Philips Respironics had received multiple complaints about the foam degradation issues; in

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constitutes inactionable puffery. *Id.* ¶ 270 (emphasis omitted); *see ECA*, 553 F.3d at 206 (explaining that statements "too general to cause a reasonable investor to rely upon them" are puffery).

November 2015, Philips Respironics failed to respond appropriately upon learning of a preventive maintenance servicing procedure on Trilogy ventilator products implemented by another KPNV subsidiary; in April 2016, field samples obtained from a Trilogy device documented foam degradation; in August and November 2016, a test report detailed foam degradation in Trilogy 200 ventilators; between 2014 and 2017, Philips Respironics had received eighty complaints related to foam degradation in non-Trilogy ventilator devices; and between 2008 and 2017, consumer complaints resulted in over 175,000 hits for the keywords "contaminants," "particles," "foam," "debris," "airway," "particulate," "airpath," and "black." *Id.* ¶ 156. Thus, Plaintiffs have alleged that, as early as 2015, Defendants knew about the foam issues and violated FDA regulations by failing to initiate corrective and preventive actions or otherwise reporting the problems. *Id.* ¶ 157.

Accordingly, certain identified statements in the Form 20-Fs are actionable. *See* SAC ¶¶ 214, 249, 283, 330–31. For instance, in the 2020 20-F, KPNV stated:

> Philips actively maintains Quality Systems globally that establish processes for its product design, manufacturing and distribution processes; these standards are in compliance with Food and Drug Administration (FDA)/International Organization for Standardization (ISO) requirements. Our business [sic] are subject to compliance with regulatory pre-marketing and quality system requirements in every market we serve, and to specific requirements of local and national regulatory authorities including the US FDA.

Id. ¶ 331 (emphases and alterations omitted). These statements were misleading for two reasons.

First, Plaintiffs have plausibly alleged that Defendants' quality control systems were not in fact in compliance with FDA regulations. *Id.* ¶¶ 156–57. Specifically, although Philips Respironics had received complaints as early as 2015, it only instituted a corrective and preventive action ("CAPA")[7] in April 2018. *Id.* ¶ 156; *see also* Form 483 at 3–4, 15. Moreover, that CAPA was "informal" and examined only Trilogy 100 and 200 devices, even though the company produced other products that employed similar designs and used PE-PUR foam. SAC ¶ 156; *see also* Form 483 at 15–19. When Philips Respironics did implement "a full-fledged CAPA" in June 2019, it remained limited to Trilogy devices and "was not adequately performed to identify[] or detect the severity or magnitude of potential quality issues/concerns." SAC ¶ 156 (internal quotation marks omitted) (quoting Form 483 at 18). Additionally, Philips Respironics and KPNV failed to report the

[7] As the Complaint explains,

> a CAPA program is a well-documented system with two components: the corrective portion identifies the root cause of non-conformances, system failures, and other problems; the preventive portion is designed to ensure that the problems do not occur in the first place (or do not reoccur after identification in the corrective portion). According to the FDA's website, "The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence." According to the FDA: "One of the most important quality system elements is the corrective and preventive action subsystem."

SAC ¶ 85.

corrective actions implemented as a result of the informal CAPA to the FDA. Form 483 at 23. Nor did they report the implementation of the CAPAs to the public until 2021. SAC ¶ 156. By failing to properly analyze or report the issues, Plaintiffs allege, KPNV was in violation of FDA regulations. *Id.* ¶ 156. Plaintiffs further plausibly allege, referencing Form 483's findings, that Defendants knew or should have known that the delay in initiating a CAPA and failure to report the problems were in violation of FDA regulations, thus rendering the statements made in the Form 20-Fs misleading. *Id.* ¶ 157.

Second, even if the statements about compliance, quality, and safety were literally true, they were nevertheless materially misleading. Literally true statements may be misleading if, in context, they would suggest to a reasonable investor that the company was in compliance. For example, in *Meyer v. JinkoSolar Holdings Co.*, the defendant-company's prospectus described its pollution abatement equipment and 24-hour monitoring teams, noted the environmental laws to which the company was subject and the consequences of noncompliance, and indicated that no such penalties had been imposed to date. 761 F.3d 245, 247–48 (2d Cir. 2014). The court explained that these statements, while "technically true," were misleading because they "gave comfort to investors that reasonably effective steps were being taken to comply with applicable environmental regulations . . . [when] in fact the equipment and 24-hour team were then failing to prevent substantial violations of the . . .

regulations." *Id.* at 251; *see also Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (describing the prospectus in *JinkoSolar* as containing "confident detail"). In contrast, a company's generalized statements about compliance have been found to be too "simple and generic" to be misleading. *See Singh*, 918 F.3d at 60, 63–64 (holding that where the defendant-company's Form 10-K "claimed to have 'established policies and procedures to comply with applicable requirements'" and "cautioned that [the company] was 'subject to numerous and complex regulations and requirements,'" those statements were "simple and generic assertions" that a reasonable investor would not have relied on as representations of satisfactory compliance).

Here, the statements in KPNV's Form 20-Fs about compliance, quality, and safety are literally true, but they are sufficiently detailed such that, in context, they would have been misleading to a reasonable investor. They point a reasonable investor to specific standards against which KPNV's quality systems could be measured, state that KPNV's quality systems were in compliance with those standards, and thereby suggest that KPNV's products met the requisite quality standards. In reality, the company was aware that foam issues and complaints had been ongoing with Philips Respironics' products since 2015, and, consequently, that the company was exposed to greater regulatory risk than its public statements let on. To be sure, KPNV need not have disclosed every complaint or potential safety issue

regarding its many products. *Cf. JinkoSolar*, 761 F.3d at 251 ("[The defendant-company's] descriptions did not guarantee 100% compliance 100% of the time. Such compliance may often be unobtainable, and reasonable investors may be deemed to know that."). But in this context, given that the foam issues were persistent and well documented, putting forth a statement suggestive of the company's regulatory compliance would have been misleading to a reasonable investor, and KPNV's discussion of the risks accompanying noncompliance do not cure that misdirection. *See id.* ("A generic warning of a risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor's calculations of probability.").

Moreover, there is no question that such statements about product safety and regulatory compliance are material. *Cf. id.* at 252 ("At the time the statements regarding pollution prevention and compliance measures were made, a reasonable investor could conclude that a substantial non-compliance would constitute a substantial threat to earnings, if not to the entire venture."). Thus, these statements about KPNV's commitment to compliance, quality, and safety are actionable.[8]

[8] In turn, those statements asserting the Form 20-Fs' compliance with the Exchange Act's reporting requirements, including that each "fairly presents, *in all material respects*, the financial condition and results of operations of the Company," are also misleading. SAC ¶ 213 (emphasis added); *see also id.* ¶¶ 248, 326.

On the other hand, several of the identified statements are inactionable because they constitute puffery. For instance, the 2018 20-F states that KPNV's businesses "play an important role on the health continuum—in the health living,

2. Statements About Business and Specific Products

Next, Plaintiffs challenge Defendants' statements about the business and specific products as materially misleading. These statements, made by van Houten and KPNV, include both general descriptions of KPNV's Connected Care businesses and descriptions of specific products, such as the Trilogy Evo, DreamStation Go, and E30. *See* SAC ¶¶ 220, 252, 257, 282, 286, 293–95, 329. Plaintiffs contend that these statements were materially misleading because they spoke positively about the business and products while omitting mention of the foam issues that posed a risk to patients' health.

While some of the identified statements are inactionable as puffery or as merely neutral descriptions of the company's products, *see id.* ¶¶ 252, 282, 329, other statements were misleading because they created the impression that the devices were well received and not the subject of significant complaints. For instance, the statements reference the "strong performance led in ventilation by the award-winning Trilogy range" and the "strong reception of the DreamStation GO expanded portable therapy options." *Id.* ¶¶ 220, 257 (emphasis omitted). Another statement by van Houten explicitly highlighted that the E30 ventilator was "an

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prevention and home care stages—delivering integrated, connected and personalized solutions that support healthier lifestyles and those living with chronic disease." SAC ¶ 250; *see also id.* ¶¶ 251, 279–81. These sorts of statements are simply "too general to cause a reasonable investor to rely upon them." *ECA*, 553 F.3d at 206.

adaptation from a bi-plane ventilator, to which we have changed the software, added sensors, added filters, so that it is safe and suitable for critical care." *Id.* ¶ 293 (emphasis omitted); *see also id.* ¶¶ 286, 294–95 (statements touting the production and function of the E30). These statements portray the various products in a wholly positive light, but to the contrary and as detailed above, Plaintiffs have alleged that, as early as 2015, Philips Respironics obtained field samples from Trilogy devices documenting foam degradation and received complaints about foam degradation in both Trilogy and non-Trilogy ventilator devices. Thus, the reality about the safety and reception of the products was significantly different from what van Houten's and KPNV's positive statements led investors to believe.

Moreover, the omission of this information was material. In the context of "adverse event reports" about a product, such reports are material if, given their source, content, and context, "a reasonable investor would have viewed the nondisclosed information as having significantly altered the total mix of information available." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43–45 (2011). Here, the omissions consist of both user complaints and the results of Philips Respironics' own testing, which corroborated those complaints. Given the sources of the information—both users and the company itself—and the information's content and context, a reasonable investor would regard it as significantly altering the total mix of information available about the devices. And contrary to Defendants' contention,

Plaintiffs need not show that Defendants knew of a significant health risk posed by the foam degradation or that a statistically significant group of users had complained. Rather, it is enough that Plaintiffs show the omitted information significantly altered the "total mix" of information available, as they have done here.

Defendants also raise the additional argument that statements about the E30, a ventilator introduced in response to the COVID-19 pandemic, were not false or misleading because the product's sale was authorized by the FDA pursuant to an Emergency Use Authorization that waived "[c]urrent good manufacturing practice requirements."[9] *See* U.S. Food & Drug Admin., Emergency Use Authorization for Ventilators and Ventilator Accessories, at 7 (Mar. 24, 2020), https://www.fda.gov/media/136423/download?attachment. But because the E30 used the same PE-PUR foam as the other devices, such statements were still misleading insofar as they led investors to believe that the E30 would be a profitable and well-received product, while omitting material information about its component foam.

[9] "Current good manufacturing practice" is a term of art, referring to the FDA requirements for quality system regulation. *See* 21 C.F.R. § 820. The requirements "govern the methods used in . . . the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." *Id.* § 820.1(a).

3. Statements About Financial Performance and Sales

Next, Plaintiffs challenge as materially misleading Defendants' statements about the financial performance and sales of the Sleep & Respiratory Care division. These statements were made by van Houten, Bhattacharya, or KPNV, primarily in quarterly earnings announcements or on quarterly earnings calls for each quarter from 2016 to 2020, as well as the first quarter of 2021; in Form 20-Fs for the years 2015 to 2020; and in the Annual Report to Shareholders for the years 2015 to 2020. *See* SAC ¶¶ 215, 217, 219, 222, 224–25, 231, 233–35, 237–39, 241–46, 253, 255, 259, 264, 266–67, 272–73, 275–76, 284, 288–91, 297–98, 300–07, 313–14, 317, 319–22, 324, 327–28, 332, 335. Two additional statements relating to financial performance were made by van Houten, one in a speech at the University of Amsterdam, and the other in an interview with Bloomberg. *See id.* ¶¶ 229, 311. Plaintiffs contend that these statements were materially misleading because they attributed KPNV's financial growth to the successful reception of the devices, while failing to disclose that such growth was unsustainable because of the foam degradation issues that would eventually come to light.

Precedent clearly forecloses this argument. As the Second Circuit has stated, "[w]hatever the scope of the responsibility not to make statements that constitute 'half-truths,' that surely does not apply to the reporting of unmanipulated corporate earnings." *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x

32, 38 (2d Cir. 2012) (summary order). Here, Defendants' statements were just that—true, unmanipulated reports of KPNV's earnings. As such, Defendants had no obligation to acknowledge any potentially unsustainable growth. *See also Novak*, 216 F.3d at 309 ("[A]s long as the public statements are consistent with reasonably available data, corporate officials need not present an overly gloomy or cautious picture of current performance and future prospects."). Thus, these statements about KPNV's financial performance are not actionable.

4. Statements About the Loan Loss Reserve and the Scope of the Foam Issues

Next, Plaintiffs allege that Defendants' statements about KPNV's €250 million loan loss provision and the scope of the PE-PUR foam degradation issues were materially misleading. On the same day in April 2021 that KPNV issued a press release disclosing the foam issues, van Houten stated on an earnings call that KPNV had taken a loan loss provision of €250 million. SAC ¶¶ 334, 336; *see also Fait v. Regions Fin. Corp.*, 655 F.3d 105, 108 n.1 (2d Cir. 2011) ("Loan loss reserves refer to the amount set aside to cover expected defaults or losses on loans."). He also stated that the problem was "related to the sound abatement foam used in certain sleep and respiratory care devices . . . primarily related to the first generation DreamStation product family," and that the occurrence rate was "very, very low, 0.03% [off] the top of my head." SAC ¶¶ 336–37. Plaintiffs allege that these statements were materially misleading because Defendants knew or were reckless in

not knowing that the €250 million loan loss provision would be inadequate, and because, by mentioning only the DreamStation products by name, Defendants failed to inform investors about the full extent of the foam issue, which also extended to other products. I disagree.

As an initial matter, there is a question as to whether the statements about the loan loss reserve are statements of fact or statements of opinion. *See Omnicare*, 575 U.S. at 183–86 (explaining the distinction). But in either case, the statements are not actionable. First, insofar as they are statements of fact that merely provide the size of the loan loss provision, the statements are inactionable because Plaintiffs allege neither that the statement was false nor any facts suggesting that €250 million—at the time the provision was taken—was an insufficient amount. *See Abramson v. NewLink Genetics Corp.*, 965 F.3d 165, 174 (2d Cir. 2020) (explaining that a statement of fact can be misleading if it lacks "the contextualization of material facts"). Rather, Plaintiffs merely state in a conclusory fashion that Defendants knew or should have known the amount would be inadequate. *See* SAC ¶ 156. And insofar as the statements are statements of opinion representing van Houten's *belief* that €250 million was a sufficient amount, the statements are inactionable because Plaintiffs have not alleged that van Houten actually disbelieved such an opinion. *See Fait*, 655 F.3d at 113 ("[I]n order for the alleged statements regarding the adequacy

of loan loss reserves to give rise to liability . . . , plaintiff must allege that defendant's opinions were both false and not honestly believed when they were made.").

Likewise, Defendants' statements about the scope of the foam issues are not misleading. In determining whether a statement is misleading, the appropriate perspective is that of the reasonable investor, and courts must consider the context in which the statement was made, "including the specificity of the representation and the authority with which it was made." *Abramson*, 965 F.3d at 175–77. Here, van Houten's statements do not suggest to a reasonable investor that *only* the DreamStation devices were affected—to the contrary, he acknowledged, in both the press release and on the earnings call, that devices in the Sleep & Respiratory Care division—which includes more than just the DreamStation products—were affected. SAC ¶¶ 334, 336. Nor do Plaintiffs allege that van Houten's mention of a low occurrence rate was false. Thus, the statements are not actionable because they cannot be construed as misleading to a reasonable investor.[10]

[10] Plaintiffs identify two additional parts of these statements as materially false and misleading. First, Plaintiffs contend that van Houten's statements blaming the use of ozone cleaner for the PE-PUR foam degradation issues, *see* SAC ¶¶ 337–38, were false (because the FDA found that ozone was not to blame) and misleading (because van Houten sought to deflect responsibility away from KPNV), *see id.* ¶ 151. These arguments fail, however, because Plaintiffs have not alleged that van Houten knew the statement was false at the time it was made, nor that investors lacked the context of material facts. That is, even if van Houten sought to deflect blame, a reasonable investor nevertheless had the relevant information about the problems then facing KPNV.

5. Statements by John Frank

Finally, Plaintiffs allege that two statements by John Frank were materially false or misleading. The first statement was made in September 2018 in connection with the launch of the Trilogy Evo ventilators. Frank briefly discussed the positive impact of "connected care" on patients and care teams dealing with chronic conditions; he then stated that the Trilogy Evo was the "next evolution of work in connected care solutions, making therapy management for chronic conditions easier and more efficient." SAC ¶ 227. The second statement was made in a July 2019 interview, where Frank discussed the role of innovation and stated, "It's in our DNA. . . . [O]ur success is based on having very deep, deep insights." *Id.* ¶ 262. Plaintiffs contend that these statements were misleading because they presented the Trilogy Evo as a positive development, but they failed to mention the foam degradation issues.

Frank's statements are not actionable because they are puffery. The first statement broadly discusses the impact of connected care before promoting the Trilogy Evo, without any specific discussion of the product. This is exactly the sort

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Second, Plaintiffs contend that KPNV's announcement of a repair-and-replace program for first-generation DreamStation devices—in which KPNV would replace the PE-PUR foam in affected devices with a silicone-based foam—was materially false and misleading because KPNV failed to disclose that the silicone-based foam had failed a safety test. *See* SAC ¶ 340. However, this statement is not actionable because Plaintiffs have not alleged that Defendants had scienter as to the problems with the silicone-based replacement foam.

of statement of corporate optimism that constitutes inactionable puffery. *See ECA*, 553 F.3d at 206 (dismissing generalizations about business practices as puffery). The second statement is even more generalized, simply touting the company as innovative and insightful without direct mention by Frank of specific products. No reasonable investor would take these statements as an indication of the good performance of specific products.

Plaintiffs also contend that statements made by the other defendants can be attributed to Frank, under the group pleading doctrine. This doctrine "creates the presumption that group-published documents such as statements in prospectuses, registration statements, annual reports, and press releases are attributable to individuals with direct involvement in the everyday business of the company, who either were or acted like a corporate insider." *Levy v. Maggiore*, 48 F. Supp. 3d 428, 448–49 (E.D.N.Y. 2014).

As a preliminary matter, the parties dispute whether the group pleading doctrine remains viable after the Supreme Court's decision in *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). Likewise, courts in this Circuit have reached different conclusions about the doctrine's continued viability. *Compare In re UBS AG Sec. Litig.*, No. 07 Civ. 11225, 2012 WL 4471265, at *10 ("[A] theory of liability premised on treating corporate insiders as a group cannot survive a plain reading of the *Janus* decision . . . ."), *aff'd sub nom. City of Pontiac*

Policemen's & Firemen's Ret. Sys. v. UBS AG, 752 F.3d 173 (2d Cir. 2014), *with Levy*, 48 F. Supp. 3d at 448 n.16 ("*Janus* addressed the liability of a party external to a corporate defendant rather than, as is the case with group pleading, the liability of individual corporate defendants."); *see also Behrendsen v. Yangtze River Port & Logistics Ltd.*, No. 19-cv-024, 2021 WL 2646353, at *10 (E.D.N.Y. June 28, 2021) (discussing this intra-circuit inconsistency).

I need not consider that issue here, however, because even assuming that the doctrine is viable, Plaintiffs nevertheless have not alleged with particularity that Frank was so involved in KPNV's day-to-day management that the corporation's statements could be attributed to him. Rather, Plaintiffs have alleged in a conclusory fashion that Frank had executive responsibility of the Sleep & Respiratory Care division and therefore supplied information about the business to KPNV for official filings. *See* SAC ¶ 413. But without anything more, such as details of Frank's responsibilities, even his high-ranking position does not permit the finding that he was a "corporate insider" at KPNV. *See Behrendsen*, 2021 WL 2646353, at *10 (finding allegations that individual defendants were "directly involved" in managing the corporation and disseminating misleading SEC filings to be "conclusory and insufficient to establish [their] liability"); *cf. Levy*, 48 F. Supp. 3d at 449–50 (finding allegations that a company's private placement memorandum listed individual defendant as "CEO and President" and "invite[d] readers to contact him to ask

questions and obtain additional information" supported the finding that he had direct involvement in the day-to-day management of the company and, therefore, could be held liable for misstatements under the group pleading doctrine). Thus, even assuming the viability of the group pleading doctrine, KPNV's statements cannot be attributed to Frank.

II. Plaintiffs' Section 20(a) Claim

Plaintiffs also bring a claim against Individual Defendants van Houten, Bhattacharya, and Frank for violations of section 20(a) of the Exchange Act in their capacities as controlling persons of KPNV. For the reasons discussed above, the first element of a section 20(a) claim, a primary violation by KPNV, has been sufficiently alleged.

Next, Plaintiffs have sufficiently alleged the second element of a section 20(a) claim, control of the primary violator by the defendant, only as to van Houten and Bhattacharya. The Complaint alleges that the Individual Defendants had the power and authority to control KPNV's SEC filings, press releases, and other communications. *See* SAC ¶¶ 63, 481. It further references van Houten's and Bhattacharya's high-ranking positions, including on KPNV's Executive Committee, as well as their frequent roles as spokespersons on behalf of the company. *See id.* ¶ 483. These factual allegations are sufficient to establish van Houten's and Bhattacharya's control over KPNV. In contrast, Plaintiffs' allegations of Frank's

control over KPNV are either conclusory or incorrect. Insofar as Plaintiffs rely on Frank's senior management positions at Philips Respironics and within the Sleep & Respiratory Care division to establish Frank's control over KPNV, *see id.* ¶¶ 481–86, the allegations do not explain how control over a subsidiary or a sector of the business equates to control over the entire company. As such, Plaintiffs have failed to sufficiently allege this element as to Frank.

Finally, Plaintiffs have satisfied the third element of a section 20(a) claim—that the defendant was a "culpable participant" in the controlled person's fraud—only as to van Houten. As discussed above, in regard to the Individual Defendants' scienter, Plaintiffs have alleged with particularity that van Houten knew or should have known about the PE-PUR foam degradation issues. It follows that van Houten knew or should have known that KPNV, by making the alleged misstatements, was engaging in fraudulent conduct. In contrast, Plaintiffs have not alleged with particularity that Bhattacharya knew about the foam issues or was otherwise aware that KPNV's statements were false or materially misleading.

Accordingly, the motion to dismiss the section 20(a) claim is granted as to Bhattacharya and Frank and denied as to van Houten.

III. Leave to Amend

In their opposition briefing on the motion to dismiss, Plaintiffs request leave to amend the Complaint. Courts should freely grant such leave "when justice so requires." Fed. R. Civ. P. 15(a)(2). However, a "district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *Holmes v. Grubman*, 568 F.3d 329, 334 (2d Cir. 2009). "A proposed amendment to a pleading would be futile if it could not withstand a motion to dismiss pursuant to Rule 12(b)(6)." *Martin v. Dickson*, 100 F. App'x 14, 16 (2d Cir. 2004) (summary order) (quoting *Oneida Indian Nation of New York v. City of Sherrill*, 337 F.3d 139, 168 (2d Cir. 2003), *reversed and remanded on other grounds*, 544 U.S. 197 (2005)).

I find that any amendment would be futile, as the sections 10(b) and 20(a) claims against Bhattacharya and the section 10(b) claim against Frank would not survive a subsequent motion to dismiss. In particular, I do not see how Plaintiffs' allegations of Bhattacharya's scienter or Frank's misstatements could be sufficient where they are wholly lacking in Plaintiffs' current Second Amended Complaint. Accordingly, Plaintiffs are denied leave to amend.

CONCLUSION

The motions to dismiss the section 10(b) and Rule 10b-5 claim are granted as against Bhattacharya and Frank and denied as against van Houten and KPNV.

Additionally, the motions to dismiss the section 20(a) claim are granted as against Bhattacharya and Frank and denied as against van Houten. The dismissed claims are dismissed with prejudice.

SO ORDERED.

Edward R. Korman

Brooklyn, New York
September 23, 2024

Edward R. Korman
United States District Judge